

### **Remarks**

While applicants respectfully submit the finality of the previous rejections was premature, nevertheless, reconsideration of the instant application is respectfully requested in light of the above-amendments and following remarks.

#### **I. STATUS OF THE CLAIMS**

Claims 1-4, 9, and 11-13 are now pending. Claim 1 has been amended to incorporate the limitations of previous claim 7. Claims 5-7 have been canceled in this amendment without prejudice. No new matter has been added.

#### **II. THE CLAIMED INVENTION IS PATENTABLE OVER SHANA'A**

The Examiner rejected the pending claims under 35 U.S.C. 103(a) as being obvious in view of U.S. Patent No. 6,737,394<sup>1</sup> issued to Shana'a (hereinafter "Shana'a"). More specifically, the Examiner asserted that Shana'a discloses isotropic cleansing compositions comprising surfactants and a thickening agent, including hydrophobically modified, crosslinked, polyacrylates. While the Examiner acknowledged that Shana'a "does not require such a composition that is free of amphoteric surfactants with sufficient specificity to constitute anticipation." Nevertheless, the Examiner concluded that "[i]t would have been obvious to a person of ordinary skill in the art at the time of the invention to have formulated a composition . . which was free of amphoteric surfactants, because such compositions fall within the scope of those taught by Shana'a et al."

In reply, applicants respectfully submit that the claimed invention is patentable over Shana'a. In particular, applicants note that not only does Shana'a fail to provide the requisite motivation to combine the teachings thereof to achieve the any particular compound having the recited combinations of anionic surfactant, hydrophobically-modified polymer, and amphoteric surfactant in the recited amounts as now claimed, but *moreover*, Shana'a fails to teach or suggest the *unexpected results* discovered by applicants to be associated with the claimed compositions

having the recited combinations of anionic surfactant, hydrophobically-modified polymer, and amphoteric surfactants in the recited amounts. In light of such unexpected results and other arguments, the claimed invention is patentable over Shana'a.

As illustrated in the attached 132 Declaration of Joseph Librizzi, applicants have discovered unexpectedly that certain hydrophobically-modified polymers can be combined with anionic surfactants to achieve compositions having surprisingly low irritation characteristics associated therewith, even in the absence of amphoteric surfactants. That is, while certain amphoteric surfactants are known to be added to compositions to reduce the irritation associated therewith, applicants have discovered that similar reduced-irritation results can be surprisingly achieved by adding hydrophobically-modified polymers to compositions comprising anionic surfactants, even in the absence of amphoteric surfactants. For example, as shown by comparing Example 23 (composition comprising no hydrophobically-modified polymer of the claimed invention nor any amphoteric surfactant) with Example 21 (same composition as Example 23 except with amphoteric added) in Tables 9, A, and B of the Declaration, the addition of amphoteric surfactant to a composition comprising anionics tends to reduce the irritation properties associated therewith. Moreover, as shown by comparing Example 23 with Example 22 (same as 23 except with a hydrophobically-modified material of the claimed invention) applicants have found that the irritation properties associated therewith are reduced significantly, and in an amount comparable to the addition of amphoteric surfactant. Such irritation-reduction properties associated with hydrophobically-modified materials, and compositions of the claimed invention comprising hydrophobically-modified materials, anionic surfactant, and less than 5% of amphoteric surfactant are, to applicants knowledge, heretofore unknown in the art.

Accordingly, applicants discovery that the specifically claimed compositions have unexpectedly low irritation properties associated therewith is clearly patentable over the mere general disclosure of Shana'a of various combinations of polymers and surfactants with no motivation or teaching of the significantly surprising results associated with the specifically claimed compositions or how to achieve such results. There is no teaching or suggestion in

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<sup>1</sup> Applicants respectfully do not necessarily agree that this reference is properly cited as prior art

Shana'a that any particular composition specifically comprising anionic surfactants, amphoteric surfactants, and the claimed hydrophobically-modified polymers combined in the required amounts and ratios are capable of producing compositions having unexpectedly low irritation properties associated therewith. Rather, the broad teaching of Shana'a suggests that a variety of compositions comprising combinations of surfactants and polymers *outside* of the claimed ranges are acceptable and equally suitable for use as those presently claimed. Accordingly, one of skill in the art would not be motivated, nor provided any suggestion, to achieve an article of the claimed invention comprising the specifically recited surfactants and polymers in the recited amounts and having the unexpected properties discovered by applicants to be associated therewith in light of the teachings Shana'a and otherwise in the art. The claimed invention is therefore patentable over the Examiner's rejection and should be allowed.

### **III. THE PROVISIONAL DOUBLE PATENTING REJECTIONS ARE RENDERED MOOT**

The Examiner maintained the provisional double patenting rejections from the previous office action. While applicants do not necessarily agree with the Examiner's rejections in any regard, nevertheless, because such provisional rejections are the only rejections remaining in view of the amendments and remarks herein, and to applicants knowledge, no patent has issued based on the above-cited applications, applicants submit such rejections should be withdrawn pursuant to MPEP 804(I)(B), and the instant case allowed. Should any of the above applications issue into a patent prior to allowance of the instant application, the Examiner is requested to contact the undersigned to allow applicants to consider filing a Terminal Disclaimer, or otherwise overcome any resulting non-provisional double patenting rejection.

### **IV. CONCLUSION**

In light of the above amendments and remarks, applicants respectfully submit the application is in condition for allowance and requests an early notice of allowance for this

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and hereby reserve the right to swear behind such reference.

application. Should the Examiner have any questions regarding this submission, please contact the undersigned.

Respectfully submitted,

/Brett T. Freeman/

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DATE: May 26, 2005



Docket No. JBP5014USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Lukenbach et al.  
Serial No. : 10/650,398 Art Unit: 1751  
Filed : 08/28/2003 Examiner: Mruk  
For : Mild and Effective Cleansing Compositions

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

May 26, 2005

(Date)

Brett Freeman

Name of applicant, assignee, or Registered Representative

Brett Freeman  
(Signature)May 26, 2005

(Date of Signature)

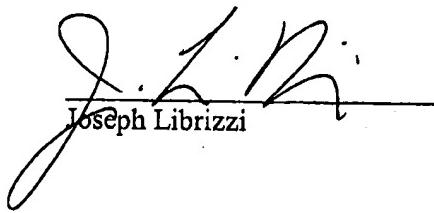
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RULE 132 DECLARATION OF JOSEPH LIBRIZZI

I, Joseph Librizzi, hereby declare and state that:

1. I am an inventor in the above-referenced patent application. I hold a B.S. degree in Electrical Engineering (1986) from Temple University and a Masters (1988) and Ph.D. (1993) in Biomedical Engineering jointly from Rutgers University and the University of Medicine and Dentistry of New Jersey. I have been employed by Johnson & Johnson Consumer Companies, Inc., the assignee of the application, and its predecessors in interest, since 1998 holding various positions including my current position as Manager of the Advanced Technologies Group. I have extensive experience and familiarity with the development of surfactant systems and cleansing composition formulations for use in consumer products.
2. I am familiar with the prosecution history of my patent application. I am aware that the invention as now claimed defines a compositions comprising certain amounts of certain hydrophobically-modified materials, anionic surfactants, and less than 0.5% amphoteric surfactants, such compositions being mild to the skin. I have reviewed the Office Action dated February 28, 2005 and the patents and patent application cited therein.
3. Attached hereto is a "Declaration Attachment" detailing the preparation of four compositions and the irritation testing data measured for each. As illustrated by the data collected and shown in Tables 9, A and B of the Declaration Attachment, applicants have demonstrated that when an amphoteric surfactant is added to a composition comprising anionic surfactant (i.e. Example 23) to achieve another composition comprising amphoteric (Example 21), the irritation associated with the composition is reduced.

4. Moreover, applicants have also surprisingly discovered and demonstrated that when a hydrophobically-modified polymer of the claimed invention is added to a composition comprising anionic surfactant (i.e. Example 23) to achieve another composition comprising hydrophobically-modified polymer and anionics, but less than 0.5% amphoteric (Example 22), the irritation associated with the composition is also significantly reduced, and reduced in an amount comparable with the amphoteric surfactant. Such irritation-reduction properties associated with hydrophobically-modified polymers, and compositions of the claimed invention comprising hydrophobically-modified polymer, anionic surfactants, and less than 0.5% amphoteric is to applicants knowledge heretofore unknown.
5. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Joseph Librizzi

5/25/05  
Date

DECLARATION ATTACHMENTExamples 20 – 23: Preparation of Cleansing Compositions

The cleansing compositions of Examples 20 through 23 were prepared according to the materials and amounts listed in Table 9.:

Table 9\*

	INCI Name	20	21	22	23
Carbopol Aqua SF-1 (30%)	Acrylates Copolymer	6.000	-----	6.000	-----
Atlas G-4280 (72%)	PEG-80 Sorbitan Laurate	4.580	4.580	-----	-----
Tegobetaine L7V (30%)	Cocamidopropyl Betaine	9.330	9.330	-----	-----
Monateric 949J (30%)	Disodium Lauroamphodiacetate	2.000	2.000	-----	-----
Cedepal TD403LD (30%)	Sodium Trideceth Sulfate	20.000	20.000	20.00	20.000
Glycerin 917 (99%)	Glycerin	1.900	1.900	1.900	1.900
Polymer JR-400	Polyquaternium-10	0.140	0.140	0.140	0.140
Dowicil 200	Quaternium-15	0.050	0.050	0.050	0.050
Versene 100XL	Tetrasodium EDTA	0.263	0.263	0.263	0.263
Sodium Hydroxide solution (20%)	Sodium Hydroxide	0.500	-----	0.500	-----
Citric Acid solution (20%)	Citric Acid	-----	0.500	-----	0.500
Water	Water	55.237	61.23 7	71.14 7	77.147

\*expressed in %w/w

The compositions of Table 9 were prepared as follows:

Water (50.0 parts) was added to a beaker. For examples 20 & 22 Carbopol Aqua SF-1 was added to the water with mixing. (For examples 21 & 23, this step was omitted.) For examples 20 & 21, Atlas G-4280 was then added to the water or water/Carbopol mixture. For examples 20 & 21, the following ingredients were added thereto independently with mixing until each respective resulting mixture was homogenous: Tegobetaine L7V, Monateric 949J, Cedepal TD403LD, Glycerin 917, Polymer JR400, Dowicil 200, and Versene 100XL. For examples 3 & 4, the Tegobetaine L7V and Monateric 949J were omitted. The pH of the resulting solution was then adjusted with either a 20% Sodium

Hydroxide solution (Examples 20 & 22) or a 20% Citric Acid solution (Examples 21 & 23) until a final pH of about 6.3 to 6.6 was obtained. The remainder of the water was then added thereto.

Mildness Comparison of Cleansing Compositions Using Skin Assay Test: The compositions prepared in accordance with Examples 20 - 23 are tested for mildness in accordance with the above Skin Assay Test at a 5% and 10% formula dilution and the results are listed below in Table 11a and 11b:

Table a: Skin Assay Test Mildness Comparison (10% dilution)

<u>Example</u>	<u>MTT value (% viability)</u>	<u>LDH value (% max release)</u>	<u>IL-1<math>\alpha</math> Value (pg/ml)</u>	<u>IL-1<math>\beta</math> Value (pg/ml)</u>
Example 20	94.2±1.8	29.4	444.2±27.5	25587.6±963.2
Example 21	84±14.7	40.2	586.4±46.4	43487.8±15177.0
Example 22	68.5±41.8	46.7	606.5±183.6	43794.9±24836.2
Example 23	61.8±5.3	54.6	652.0±10.8	53190.6±12253.3

Table B: Skin Assay Test Mildness Comparison (5% dilution)

<u>Example</u>	<u>MTT value (% viability)</u>	<u>LDH value (% max release)</u>	<u>IL-1<math>\alpha</math> Value (pg/ml)</u>	<u>IL-1<math>\beta</math> Value (pg/ml)</u>
Example 20	99.5±2.4	21.8	336.8±150.2	19772.5±3104.0
Example 21	95.7±9.0	19	372.7±120.8	30368.8±6597.4
Example 22	96.5±1.4	29.9	545.8±124.8	25883.0±10841.9
Example 23	89.3±3.1	34.2	544.0±52.7	27585.6±8087.1

The MTT viability assay is a measure of metabolic viability based on the reduction of MTT dye by the cells. MTT viability results are used to identify the most severe irritants. Results are reported as Percent of Untreated Control Value, therefore, 100% would indicate no loss of viability. From the results, it is clear that Example 20, possessing both amphoteric and hydrophobically modified, crosslinked polymer, were the mildest at both 5% and 10% formula dilutions. Example 21 (containing amphoteric without hydrophobically modified, crosslinked polymer) and Example 22 (containing hydrophobically modified, crosslinked polymer without amphoteric) gave comparable

viability scores in both 5% and 10% dilutions. Example 23, possessing neither amphoteric nor hydrophobically modified, crosslinked polymer, yielded the lowest viability scores at both 5% and 10% dilutions and therefore is the least mild of the group. This indicates that the hydrophobically modified crosslinked polymer possesses similar irritation mitigation as an amphoteric in a cleansing system and the combination has an additive effect as indicated in Example 20.

The LDH assay is a colorimetric assay for the quantification of cell death and damage, based on the measurement of lactate dehydrogenase (LDH) activity released from the cytosol of cells with damaged or lysing membranes. Surfactants are known to cause cell death through rapid disruption of cell membranes. Results are reported as Percent of Maximum Leakage, therefore, 100% would indicate total loss of viability. Results of this test follow the same trends as MTT viability assay data in that Example 20, possessing both amphoteric and hydrophobically modified, crosslinked polymer, demonstrates the lowest scores (most mild), Examples 21 (containing amphoteric without hydrophobically modified, crosslinked polymer) and 22 (containing hydrophobically modified, crosslinked polymer without amphoteric) exhibits similar scores (equivalent mildness) and Example 23, possessing neither amphoteric nor hydrophobically modified, crosslinked polymer, yielded the highest scores at both 5% and 10% dilutions and therefore is the least mild of the group.

IL-1alpha (IL-1a) and IL1 receptor antagonist (IL1ra) release in skin equivalents is relative to the degree of irritation potential and are expressed as Percent of Untreated Control. High values of IL-1a and IL1ra are indicative of irritating formulas. Once again the trends of this data are similar to those of the MTT viability test and LDH assay in that Example 20, possessing both amphoteric and hydrophobically modified, crosslinked polymer, demonstrates the lowest scores (most mild), Examples 21 (containing amphoteric without hydrophobically modified, crosslinked polymer) and 22 (containing hydrophobically modified, crosslinked polymer without amphoteric) exhibits similar scores (equivalent mildness) and Example 23, possessing neither amphoteric nor

hydrophobically modified, crosslinked polymer, yielded the highest scores at both 5% and 10% dilutions and therefore is the least mild of the group.

From these results, it can be concluded that the hydrophobically modified, crosslinked polymer acts in a similar way to amphoteric in its ability to reduce irritation of a cleansing system. Furthermore, it is clear that when amphoteric are combined with the hydrophobically modified, crosslinked polymer a surprising additive effect in reducing irritation is noted.